

Date: May 4, 1998

ASSISTANT COMMISSIONER FOR PATENTS  
Washington, DC 20231

Sir:

Transmitted herewith for filing is the patent application of:

Inventor: Milton HODOSH

For: **METHOD AND COMPOSITION FOR PREVENTING TOOTH  
HYPERSENSITIVITY WHEN USING PASSIVE BLEACHING AGENTS**

Enclosed are:

- ☒ Verified Statement (Declaration) Claiming Small Entity Status - Independent Inventor  
☒ Verified Statement (Declaration) Claiming Small Entity Status - Small Business Concern  
☒ Executed Declaration and Power of Attorney  
☒ Information Disclosure Statement, Form PTO-1449 and references cited therein

The filing fee has been calculated as shown below:

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INDEP. CLAIMS	4 - 3 =	*1	x \$ 41	\$ 41		x \$ 82	\$
[ ] MULTIPLE DEPENDENT CLAIM PRESENTED			+ \$135	\$		+ \$270	\$

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STEINBERG &amp; RASKIN, P.C.

By: 

Martin G. Raskin  
Reg. No. 25,642

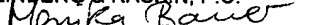
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STEINBERG &amp; RASKIN, P.C.

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05072504 10304408

**UNITED STATES PATENT AND TRADEMARK OFFICE**

In re:                      Application of:              Milton HODOSH

                                 Serial No.:                      Not yet known

                                 Filed:                              Simultaneously

                                 For:                                METHOD AND COMPOSITION FOR  
   PREVENTING TOOTH HYPERSENSITIVITY  
   WHEN USING PASSIVE BLEACHING AGENTS

**VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS  
[37 CFR 1.9(f) and 1.27(b)] - Independent Inventor**

Honorable Commissioner of Patents and Trademarks  
Washington, D.C. 20231

Sir:

As a below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees under section 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention entitled METHOD AND COMPOSITION FOR PREVENTING TOOTH HYPERSENSITIVITY WHEN USING PASSIVE BLEACHING AGENTS described in

☒ the specification filed herewith.  
☐ application serial no. \_\_\_\_ filed \_\_\_\_.  
☐ patent no. \_\_\_\_ issued \_\_\_\_.

I have not assigned, granted, conveyed or licensed and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

☐ no such person, concern, or organization.  
☒ persons, concerns or organizations listed below\*.

\*NOTE: Separate verified statements are required from each named person, concern, or organization having rights to the invention averring to their status as small entities.

(37 CFR 1.27)

FULL NAME Sultan Chemists, Inc.

ADDRESS 85 West Forest Avenue

Englewood, New Jersey 07631

☒ INDIVIDUAL      ☐ SMALL BUSINESS CONCERN      ☐ NONPROFIT  
ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. [37 CFR 1.28 (b)]

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, and patent issuing thereon, or any patent to which this verified statement is directed.

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Milton Hodosh, D.M.D.  
Milton Hodosh, D.M.D.

3-9/98  
Date

**UNITED STATES PATENT AND TRADEMARK OFFICE**

In re:                      Application of:              Milton HODOSH

                                 Serial No.:                      Not yet known

                                 Filed:                              Simultaneously

                                 For:                                METHOD AND COMPOSITION FOR  
   PREVENTING TOOTH HYPERSENSITIVITY  
   WHEN USING PASSIVE BLEACHING AGENTS

**VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS**  
**[37 CFR 1.9(f) and 1.27(c)] - Small Business Concern**

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Assistant Commissioner of Patents  
Washington, D.C. 20231

Sir:

I hereby declare that I am

☐ the owner of the small business concern identified below:  
☒ an official of the small business concern empowered to act in behalf of the  
concern identified below:

Name of concern Sultan Chemists, Inc.  
Address of concern 85 West Forest Avenue  
Englewood, New Jersey 07631

I hereby declare that the above identified small business concern qualifies as a small business concern as defined in 37 CFR 1.9(d), for purposes of paying reduced fees under section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the person employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern and/or there is an obligation under contract or law by the inventor(s) to

convey rights to the small business concern with regard to the invention, entitled METHOD OF PREVENTING TOOTH HYPERSENSITIVITY WHEN USING PASSIVE BLEACHING AGENTS by inventor Milton HODOSH described in

[X] the specification filed herewith  
[ ] application serial no. filed  
[ ] patent no. issued

If the rights held by the above identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below and no rights to the invention are held by any person, other than the inventor, who could not qualify as an independent inventor under 37 CFR 1.9(c) if that person made the invention, or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d), or a nonprofit organization under 37 CFR 1.9(e).

FULL NAME \_\_\_\_\_

ADDRESS \_\_\_\_\_

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, and patent issuing thereon, or any patent to which this verified statement is directed.

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Name of person signing \_\_\_\_\_

Title of person other than owner \_\_\_\_\_

Address of person signing \_\_\_\_\_

Englewood, N.J. 07631

Signature \_\_\_\_\_

Date 3/11/98

\*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities.  
(37 CFR 1.27)

U.S.A.  
**DECLARATION AND POWER OF ATTORNEY**

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

METHOD AND COMPOSITION FOR PREVENTING TOOTH HYPERSENSITIVITY WHEN USING PASSIVE BLEACHING AGENTS the specification of which (check one)

  X   is attached hereto.

           was filed on                      as Application Serial No.                      and was amended on                      (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose all information which is known to me to be material to the patentability of this application as defined in Title 37, Code of Federal Regulations, §1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed.

PRIOR FOREIGN APPLICATION(S)

Priority claimed

<u>                    </u> (Number)	<u>                    </u> (Country)	<u>                    </u> (Day/Month/Year Filed)	<u>      </u> <u>      </u> Yes No
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I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

<u>                    </u> (Application Serial Number)	<u>                    </u> (Filing Date)	<u>                    </u> (Status) (patented, pending, abandoned)
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And I hereby appoint

Martin G. Raskin, Registration No. 25,642,  
 Clifford M. Davidson, Registration No. 32,728,  
 Brian Roffe, Registration No. 35,336,

James R. Crawford, Registration No. 39,155,  
Leslye B. Davidson, Registration No. 38,854,  
Cary S. Kappel, Registration No. 36,561, and  
Joshua L. Raskin, Registration No. 40,135

my attorneys, with full power of substitution and revocation, to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith; correspondence address:

STEINBERG, RASKIN & DAVIDSON, P.C.,  
1140 Avenue of the Americas,  
New York, N.Y. 10036;  
Telephone: (212) 768-3800; Fax: (212) 382-2124.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or first

Inventor Milton HODOSH

Inventor's signature Milton Hodosh, S.M.D.

Date 3/9/98

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**METHOD AND COMPOSITION FOR PREVENTING  
TOOTH HYPERSENSITIVITY WHEN USING  
PASSIVE BLEACHING AGENTS**

**FIELD OF THE INVENTION**

This invention is in the field of compositions and methods of treatment for dental bleaching agents, and more specifically in the prevention of post-bleaching induced hypersensitivity.

**BACKGROUND OF THE INVENTION**

The process of dental bleaching is an increasingly popular practice in dentistry to combat the problem of staining or discoloration of teeth.

The enamel layer of teeth is composed of hydroxyapatite. It is believed that the porous nature of the enamel is attributed to the crystalline structure of hydroxyapatite, which allows staining agents and discoloring substances to permeate the enamel, thereby discoloring teeth. Substances that come in contact daily with teeth and that can stain or reduce the "whiteness" of teeth include foods, tobacco products, tea, coffee, betel nut, plants and food products. These substances permeate the enamel of the teeth and with continued contact impart noticeable discoloration to the teeth.

In addition, teeth may become stained from excessive intake of fluoride (endemic fluorosis). In young persons, the administration of tetracycline during tooth formation may cause staining. Generalized intrinsic staining can result from systemic conditions and diseases such as cystic fibrosis, congenital hematuria and dentinogenesis imperfecta.

Since white or unstained teeth are considered to improve a person's appearance, it is generally desired by patients to try to increase the whiteness of the teeth. Methods of improving the whiteness of teeth include bleaching methods which can be used to ameliorate the staining of



teeth. However, known effective bleaching procedures for teeth also result in the undesired effect of tending to produce hypersensitivity or supersensitivity of the teeth. It has been reported that 74% of incidents of dental bleaching result in post-bleaching pain (hypersensitivity) to the patient. Bleaching compositions generally use peroxide or peroxide yielding compounds which have tended to involve the activation of peroxide by light sources such as photo flood light, ultraviolet light, or by heat methods such as convection heat or by the application of heat directly to teeth. These methods require the use of high concentrations of peroxide, such as in the form of Superoxol® or a 35% peroxide composition, which not only cause hypersensitivity but also have the potential to damage oral and facial tissues.

Passive bleaching involves the use of bleaching agents supplied directly in dentrifice compositions for brushing the teeth, or gels, foams, creams or pastes which are applied in prefabricated trays and/or in custom trays fabricated with reservoirs to hold bleaching preparations in extended intimate contact with the teeth for longer periods of time. Passive bleaching agents have been used with photo flood lights and with lasers. It is now understood that the teeth can be made whiter by passive bleaching methods using peroxide releasing compounds such as carbamide peroxide, also known as urea peroxide, usually in the amount of 10% to 20% by weight of the composition. The higher concentrations of the peroxide yielding compounds are used to effect faster and more effective bleaching (power bleaching). Other peroxide releasing compounds that have been known in the prior art include sodium perborate, zinc peroxide, calcium peroxide and magnesium peroxide, and other compounds which can release peroxide effectively with bubbling oxidizing force.

In general, higher concentrations of peroxide yielding compounds improve the efficacious bleaching capabilities of the composition. However, the higher peroxide concentrations exacerbate the sequelae of hypersensitivity or supersensitivity. The pain resulting from hypersensitivity or supersensitivity is considered to be a warning that the tooth and pulpal tissues have experienced a severe insult. Faster and more aggressive bleaching techniques, such as with the use of higher concentrations of peroxide yielding compounds, results in more severe and higher incidence of post-bleaching hypersensitivity to thermal, chemical and tactile stimuli.

Dental bleaching compositions are described in a number of references, including U.S.

Patent No. 5,098,303; U.S. Patent No. 5,234,342; U.S. Patent No. 5,376,006; and U.S. Patent No. 5, 409,631, all to Fischer, which are hereby incorporated by reference. The Fisher patents describe tooth bleaching dental gel composition comprising carbamide peroxide, water, glycerin, carboxypolymethylene (Carbopol) and sodium hydroxide. Dental bleaching compositions are also described in U.S. Patent No. 5,631,000, to Pellico et al., which is hereby incorporated by reference.

The use of potassium nitrate as a compound for desensitizing teeth is disclosed in U.S. Patent No. 3,863,006, which is hereby incorporated by reference. Potassium nitrate has also been disclosed as useful for treatment of canker sores in U.S. Patent No. 4,191,750, hereby incorporated by reference; useful for preserving dental pulp, in U.S. Patent No. 4,343,608, hereby incorporated by reference; useful for treating gingival and periodontal tissues, in U.S. Patent No. 4,400,373, hereby incorporated by reference; and useful for treating post-restoration dental pain, in U.S. Patent No. 5,153,006, hereby incorporated by reference.

Other patents, including for example U.S. Patent No. 5,256,402 and U.S. Patent No. 5,648,399, have described the use of potassium nitrate in dentrifice compositions as a treatment for hypersensitivity. However, the use of potassium nitrate incorporated into dental tray bleaching compositions has not been previously described as being capable of preventing tooth hypersensitivity.

Another patent, U.S. Patent No. 5,522,726 has described the use of a composition having a high concentration of potassium, such as potassium nitrate, for anesthetizing teeth requiring preparation, caries removal or manual manipulation thereof.

### **SUMMARY OF THE INVENTION**

It has now been surprisingly discovered that the use of 1% to 35% of a potassium-containing composition, such as potassium nitrate, by weight in passive bleaching materials comprising a peroxide releasing material prevents the frequently seen (up to 75% of the time) tooth hypersensitivity from occurring. The potassium nitrate contemplated by the invention is uniquely compatible with peroxide yielding bleaching compounds such as peroxide, carbamide peroxide, calcium peroxide, zinc peroxide, magnesium peroxide and sodium perborate.

In another aspect of the invention, it has also been found that the potassium-containing composition, specifically potassium nitrate, which is known to be an oxidizing agent, is complimentary and synergistic with the peroxide bleaching agents contemplated by the invention and actually enhances the release of oxygen to the tooth enamel.

5 Preferred compositions of the invention may include from 1% to 35% by weight of potassium nitrate. In more preferred compositions of the invention, the potassium nitrate is present in the amount of 1-20%. In even more preferred embodiments, potassium nitrate is present in the amount of 1-8%. In a most preferred embodiment, potassium nitrate is present in a composition in the amount of about 5% by weight. The invention contemplates the use of higher  
10 amounts of potassium nitrate with higher amounts of peroxide releasing compounds.

The invention also contemplates the use of a potassium-containing composition comprising a compound other than potassium nitrate such as potassium bicarbonate, potassium biphthalate, potassium bromide, potassium chromate, potassium dichromate, potassium phosphate, potassium sulfate, potassium chromium sulfate, potassium thiocyanate, potassium alum, potassium bitartrate, potassium bromate, potassium carbonate, potassium chlorate, potassium chloroglatinate, potassium hydroxide, potassium perchlorate, potassium persulfate, potassium oxalate, potassium azide, potassium flouride, potassium hydrogen sulfate, potassium iodate, potassium chloride, potassium acetate or potassium tartrate. For the purposes of the invention and the description herein, these potassium-containing compounds may be used instead  
15 of potassium nitrate.  
20

The invention contemplates the use of the potassium-containing compound such as potassium nitrate in liquids, gels, creams, pastes, foams and ointments with tooth bleaching compositions for the prevention of tooth hypersensitivity from occurring. In an additional embodiment, the invention is in the form of a lacquer or varnish or other surface coating that is  
25 painted to the teeth, thereby providing a longer contact/coating period. In all embodiments of the invention, the use of the potassium-containing compound such as potassium nitrate is a unique one-step method of preventing hypersensitivity when combined with the bleaching compositions known in the art, and is different from known methods of using potassium-containing compounds potassium nitrate for the treatment of hypersensitivity that has already occurred. This is an

improvement over the known use methods of this technology, and the invention is directed to a method of preventing the usual tooth hypersensitivity from occurring following the application of the dental bleaching composition of the invention to teeth.

5

## **DETAILED DESCRIPTION OF THE INVENTION**

By "orally compatible" is meant compositions and ingredients which are generally regarded as safe for use in the oral cavity.

10

By "oral compositions" is meant a product which in the ordinary course of its use is retained in the oral cavity for a time sufficient to contact substantially all of the dental surfaces and/or oral tissues for purposes of oral activity.

By "safe and effective amount" is meant a sufficient amount of material to provide the desired benefit while being safe to the hard and soft tissues of the oral cavity.

15

By "carrier" is meant a suitable vehicle which is orally compatible and can be used to apply the present compositions in the oral cavity.

20

It is to be noted that the composition of the invention is a dental bleaching composition, and can be distinguished from dentrifies. A "dentrifice" is a substance, such as a liquid, paste, gel or powder, used with a toothbrush or similar instrument for the purpose of cleaning the accessible parts of teeth. Dentrifies generally contain a fluoride releasing compound and an abrasive.

25

The bleaching composition of the invention may take the form of liquids, gels, pastes, creams, ointments or foams. In each of these forms, the bleaching composition of the invention includes a peroxide releasing compound, such as carbamide peroxide (Peroxomer®), and potassium nitrate in the amount of from 1% to 35% by weight. Other potassium-containing compounds instead of potassium nitrate, such as those listed above, may be used instead of potassium nitrate in the bleaching composition.

The bleaching compositions of the present invention can also include ancillary ingredients such as orally compatible carriers or matrices, to provide commercially acceptable products. The carrier for the dental bleaching compositions of the invention include water. The water used in

the compositions of the invention is preferably deionized and free of impurities. Water may comprise up to about 50%, preferably from about 20% to about 40%, by weight of the dental bleaching composition herein.

5 The composition of the invention may also include glycerin, which acts as a humectant and  
flavoring agent, or sorbitol, aloes such as aloe vera, polyethylene glycols, propylene glycols,  
polyols or polypropylene. Flavoring agents which may be included in the composition of the  
invention include mint flavorings, oil of wintergreen, oil of peppermint, oil of spearmint, oil of  
sassafras, and oil of clove. Sweetening agents may also be used, and include xylitol, aspartame,  
acesulfame, saccharin, dextrose, levulose and sodium cyclamate. Flavoring and sweetening agents  
10 are generally included in the dental bleaching compositions of the invention in the amount of from  
about 0.005% to about 2% by weight. Combinations of one or more humectants, flavoring agents  
or sweetening agents is also contemplated by the invention.

The composition of the invention may comprise a high viscosity matrix material, such as  
carboxypolymethylene (Carbopol).

15 A water soluble cellulosic ether, such as hydroxyalkyl celluloses such as hydroxypropyl  
cellulose, hydroxypropyl ethylcellulose, or hydroxypropyl methylcellulose, or carboxymethyl  
cellulose, may also be included in the dental bleaching composition. Further, the composition may  
comprise a base, such as sodium hydroxide.

20 The composition may also comprise orally compatible preservatives of the type commonly  
used in dental compositions, such as sodium benzoate.

The composition may also comprise orally compatible coloring agents or colorants of the  
type commonly used in dental compositions.

25 In the form of a gel, glycerin may be present in the amount up to about 64% by weight;  
propylene glycol may be present in the amount of up to about 55% by weight; polyethylene glycol  
may be present in the amount of up to about 50% by weight; deionized water may be present in  
the amount of up to about 50% by weight; carboxypolymethylene may be present in the amount  
of up to about 12% by weight; hydroxyalkyl cellulose may be present in the amount of up to  
about 15% by weight; carbamide peroxide may be present in the amount of about up to about  
30% by weight; and potassium nitrate may be present in the amount of about 1% by weight to

35% by weight. Other potassium-containing compounds instead of potassium nitrate, such as those listed above, may be used instead of potassium nitrate in the gel.

The composition of the invention in its liquid form, such as in the form of a solution, includes an orally compatible solvent, such that the solvent may come into contact with the dental and gingival tissues of a person. Suitable solvents include water and water-immiscible solvents, such as ethanol, isopropyl alcohol, propylene glycol, polyethylene glycol, glycerol, methylcellulose, cellulose, esters, morpholines, dioxane, dimethylsulphoxide and the like. The composition of the invention in the form of a liquid may also comprise a stabilizer, such as calcium disodium edetate, deforoxamine mesylate or tetrasodium edetate.

In its embodiment as a foam, the composition of the invention may include any of the various types of emulsifying agents or surfactants commonly used in dental compositions. Exemplary emulsifying agents are those which are reasonably stable and foam throughout a wide pH range, including non-soap anionic, nonionic, cationic, zwitterionic and amphoteric organic synthetic detergents.

In addition to the higher fatty acid soaps, other synthetic anionic organic detergents may be used as replacements or partial replacements. Among the useful anionic detergents are the higher alkyl sulfates, higher alkyl sulfonates, higher alkyl benzene sulfonates, ethoxylated higher fatty alcohol sulfates, monoglyceride sulfates, higher fatty acid amides of amino-lower carboxylic acids, such as sodium lauroyl sarcoside, phosphates and phosphonates corresponding to the above mentioned sulfates and sulfonates, and sulfates and sulfonates of the well-known nonionic surface active agents, such as those of polyoxyethylene glycols, of block copolymers of ethylene oxide and propylene oxide, chain terminated with propylene glycol and of polyethoxylated middle alkyl phenols. Specific examples of useful anionic synthetic organic detergents or surface active agents for inclusion in this formula are: triethanolamine lauryl sulfate; linear dodecyl benzene sodium sulfonate; potassium coconut oil monoglyceride sulfate; ammonium paraffin sulfonate; and ammonium paraffin sulfonate and ammonium polyoxyethylene stearyl alcohol sulfate.

The foam composition of the invention may also include a foam stabilizer or mixture of such stabilizers. Such materials may include organic gums and colloids, serving as thickening agents to maintain the foam in the shape in which it was applied, but it will often be found

preferable to utilize the lower alkanolamides of higher fatty acids for this purpose. An exemplary foam stabilizer is lauric-myristic diethanolamide, or LMDEA.

In its various embodiments, the composition of the invention may be within a range of pH's which are safe for the hard and soft tissue of the mouth. Such pH's are generally from about 3 to about 10, preferably from about 4 to about 8.

The dental bleaching composition of the invention is designed for application to teeth by methods commonly used in the art. For example, the composition may be disposed in a applicator tray which is insertable into the mouth as a mouthpiece surrounding respectively the upper and lower teeth and adjacent periodontal tissue. Such trays are commonly rigid and made of the vinyl plastic material and are in the form of an arcuate U-shaped mouth piece. Applicator trays are described in U.S. Pat. No. 5,575,654, to Fontenot, which is hereby incorporated by reference.

### EXAMPLES

The following Examples illustrate various exemplary formulations of the compositions of the invention in the form of gels.

TABLE I

Example

	1	2	3
Carbamide peroxide	10%	20%	14%
Water (deionized)	21%	20%	10%
Potassium Nitrate	5%	7%	6%
Glycerin	52%	33%	64%
Hydroxyalkyl Cellulose	7%	12%	3.5%
Sodium Hydroxide	5%	8%	2.5%

Set forth in Table I above are three examples of formulations of the invention in the form of gels. It is noted that Example 2, with the highest concentration of carbamide peroxide, has similarly higher percentages of potassium nitrate for best effects. For maximum results a dental tray holds these preparations adjacent to discolored tooth surfaces.

The use of hydroxyalkyl cellulose results in bleaching compositions of high viscosity. As a result, the dilution of compositions by saliva is difficult, and the composition stays within the tray longer providing a sustained relief of the effect of the peroxide releasing properties of the carbamide peroxide to the patient's teeth.

A fourth example of the composition of the invention in the form of a gel is set forth below at Table II with its components in weight percent.

**TABLE II**

**Example 4**

Water (deionized)	6%
Propylene Glycol	32%
Glycerin	38%
Xylitol	9%
Peroxomer® 407	7%
Potassium Nitrate	3%
Aloe Vera	3%
Mint or other flavoring	2%

Example 4 is used preferably with a dual chamber dental tray as hydrogen peroxide is stable at lower pH's but is effective at higher pH's. The dual chamber tray contains an activator and mixes the compositions together.

A fifth example of the composition of the invention in the form of a gel is set forth below in Table III with its components in weight percents.



**TABLE III**

**Example 5**

Carbamide Peroxide	17%
Water (deionized)	2%
Hydroxyethyl cellulose	14%
Potassium nitrate	33%
Carbopol	30%
Flavoring agents	2%
Coloring agents	2%

The compositions of the invention may be formed by any of the methods commonly used in the art, such as by adding and admixing the ingredients in a suitable vessel, for example a stainless steel tank. Mixers may be used to mix the ingredients to form a homogeneous dispersion such as a gel. The components that are mixed together are added in amounts to produce a resulting composition with the weight percents disclosed in this specification, for example in the above Examples 1 to 5.

It is understood that upon prolonged storage or upon use, such as upon disposal into dental trays or upon contact with a patient's teeth, the compositions of the invention may undergo chemical or physical reactions so that the chemical nature of the components are changed. For example, as described above the carbamide peroxide or other peroxide releasing compound decomposes over time so that peroxide is released. Further, the humectants such as propylene glycol, may absorb water to form new compounds. It is understood that these chemical and physical reactions may change the weight percents of the composition that are present at formation.

While there have been described particular embodiments of the invention, those skilled in the art will realize that changes and modifications can be made thereto without departing from the spirit of the invention and it is intended to claim all such changes and modifications that fall within the true scope of the invention.

## **CLAIMS:**

Having thus described the invention, what is claimed is:

1. An orally compatible composition comprising a peroxide releasing tooth bleaching compound and from 1% to 35% by weight of potassium-containing compound, wherein said potassium-containing compound is present in a safe and effective amount to prevent tooth hypersensitivity from occurring upon application of the tooth bleaching composition to teeth.
2. The orally compatible composition of claim 1, wherein said peroxide releasing compound is selected from the group consisting of carbamide peroxide, sodium perborate, zinc peroxide, calcium peroxide, and magnesium peroxide, and mixtures thereof.
3. The orally compatible composition of claim 1, wherein said potassium-containing compound is potassium nitrate.
4. The orally compatible composition of claim 3, wherein said potassium nitrate is present in the amount of from 1% - 20% by weight.
5. The orally compatible composition of claim 3, wherein said potassium nitrate is present in the amount of from 1% - 8% by weight.
6. The orally compatible composition of claim 3, wherein said potassium nitrate is present in the amount of about 5% by weight.
7. The orally compatible composition of claim 1, wherein said composition is selected from the group consisting of liquids, gels, pastes, creams, ointments and foams.
8. The orally compatible composition of claim 1, wherein said potassium-containing compound is selected from a group consisting of potassium bicarbonate, potassium biphthalate,

potassium bromide, potassium chromate, potassium dichromate, potassium phosphate, potassium sulfate, potassium chromium sulfate, potassium thiocyanate, potassium alum, potassium bitartrate, potassium bromate, potassium carbonate, potassium chlorate, potassium chloroglatinate, potassium hydroxide, potassium perchlorate, potassium persulfate, potassium oxalate, potassium azide, potassium fluoride, potassium hydrogen sulfate, potassium iodate, potassium chloride, potassium acetate and potassium tartrate.

9. An orally compatible dental bleaching gel comprising
  - (a) from 10 to 20 % by weight carbamide peroxide;
  - (b) from 10 to 25 % by weight deionized water;
  - (c) from 5 to 7 % by weight a potassium-containing compound; and
  - (d) from 30 to 65 % by weight glycerin.
10. The gel of claim 9, further comprising sodium hydroxide.
11. The gel of claim 10, further comprising a high viscosity matrix material.
12. The gel of claim 11, wherein said high viscosity matrix material is carboxypolymethylene.
13. The gel of claim 10, further comprising hydroxyalkyl cellulose.
14. The gel of claim 13, further comprising a sweetening agent.
15. The gel of claim 9, further comprising a flavoring agent.
16. The gel of claim 9, wherein said potassium-containing compound is potassium nitrate.

17. The gel of claim 9, wherein said potassium-containing compound is selected from a group consisting of potassium bicarbonate, potassium biphthalate, potassium bromide, potassium chromate, potassium dichromate, potassium phosphate, potassium sulfate, potassium chromium sulfate, potassium thiocyanate, potassium alum, potassium bitartrate, potassium bromate, potassium carbonate, potassium chlorate, potassium chloroglatinate, potassium hydroxide, potassium perchlorate, potassium persulfate, potassium oxalate, potassium azide, potassium flouride, potassium hydrogen sulfate, potassium iodate, potassium chloride, potassium acetate and potassium tartrate.

18. An orally compatible dental bleaching gel comprising

- (a) from 5 to 10 % by weight carbamide peroxide;
- (b) from 5 to 10 % by weight deionized water;
- (c) from 3 to 5 % by weight a potassium-containing compound; and
- (d) from 30 to 40 % by weight glycerin; and
- (e) from 30 to 35 % by weight propylene glycol.

19. The gel of claim 18, further comprising a sweetening agent.

20. The gel of claim 18, further comprising a flavoring agent.

21. The gel of claim 18, wherein said potassium-containing compound is potassium nitrate.

22. The gel of claim 18, wherein said potassium-containing compound is selected from a group consisting of potassium bicarbonate, potassium biphthalate, potassium bromide, potassium chromate, potassium dichromate, potassium phosphate, potassium sulfate, potassium chromium sulfate, potassium thiocyanate, potassium alum, potassium bitartrate, potassium bromate, potassium carbonate, potassium chlorate, potassium chloroglatinate, potassium hydroxide, potassium perchlorate, potassium persulfate, potassium oxalate, potassium azide,

potassium flouride, potassium hydrogen sulfate, potassium iodate, potassium chloride, potassium acetate and potassium tartrate.

23. A method of preventing tooth hypersensitivity in a patient undergoing dental bleaching, comprising the step of:

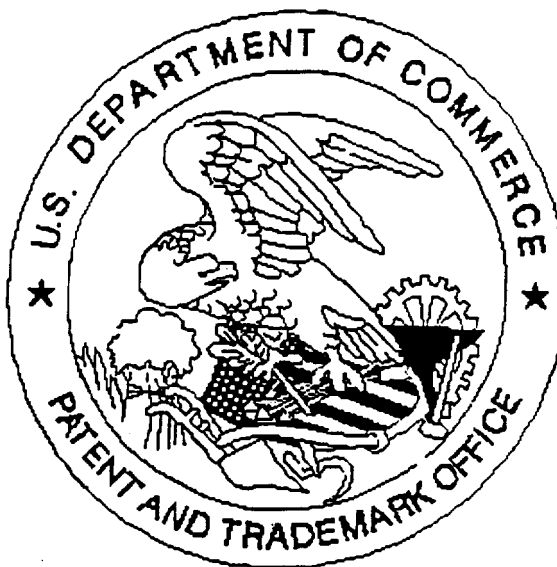
applying a dental bleaching composition to the teeth comprising a peroxide releasing compound and from 1% to 35% by weight a potassium-containing compound, wherein said potassium-containing compound is present in a safe and effective amount to prevent tooth hypersensitivity upon application of the composition to teeth.

24. The method of claim 23, wherein said potassium-containing compound is potassium nitrate.

25. The method of claim 23, wherein said potassium-containing compound is selected from a group consisting of potassium bicarbonate, potassium biphthalate, potassium bromide, potassium chromate, potassium dichromate, potassium phosphate, potassium sulfate, potassium chromium sulfate, potassium thiocyanate, potassium alum, potassium bitartrate, potassium bromate, potassium carbonate, potassium chlorate, potassium chloroglatinate, potassium hydroxide, potassium perchlorate, potassium persulfate, potassium oxalate, potassium azide, potassium flouride, potassium hydrogen sulfate, potassium iodate, potassium chloride, potassium acetate and potassium tartrate.

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